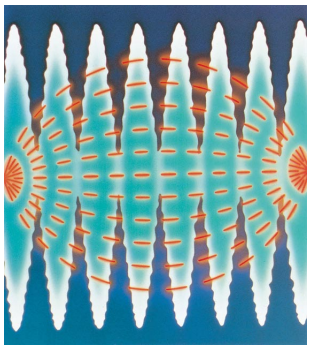
Ultrasound Therapy Device



SONOSTAT 133

User manual

Version 1.3

The gbo Medizintechnik AG has taken care in preparation of this manual, but makes no expressed or implied warranty of any kind and assume no responsibility for errors or omissions.

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Notations

Times New Roman in type size 11	- descriptions and explanations;
Arial in type size 10	- functions and control keys of the device;
Lucida in type size 10 or 11	- text appears on the display of the device;

Warnings and safety precautions

Warning!

Warnings which have to be observed by all means!

Caution!

Observe the instructions for use!

Note!

Information that will facilitate your work.

Contents

1 Introduction

1.1 Intended Use

The **SONOSTAT 133** is a classical ultrasound therapy device for constant and pulsed ultrasound. All applications are to be executed with easy and safety.

The ultrasonic therapy device **SONOSTAT 133** generates ultrasound waves by means of the two main components, the generator and the treatment probe. The resulting effects may be distinguished as follows:

a) Mechanical effects (primary effect)

The ultrasound wave causes a vibration and acceleration of the mass particles in the exposed tissue (high-frequency vibration massage).

b) Thermal effects (primary effect)

The temperature in the area of the exposed tissue rises locally. The energy flow and temperature in the tissue being treated is determined by the absorption and reflection of ultrasound. This will vary greatly according to the tissue involved.

c) Piezoelectric effect (primary effect)

Under alternating mechanical pressure, electrical potentials are induced which increase cell activity, particularly in bones.

In addition: biological effects (secondary effect)

Due to thermal and mechanical processes, biological effects such as increased membrane permeability and vascular dilation are achieved. As a consequence, the patient experiences a relief from pain.

Due to its mechanical, thermal, chemical and biological effects, ultrasound can be effectively used for the treatment of:

- inflammatory, rheumatic diseases of the muscoloskeletal system
- traumatic affections such as contusions, distortions or contractures
- inflammatory diseases of the peripheral nerves (neuritis or neuralgias)
- peripheral circulatory and inflammatory diseases.

The range of application is extended by pulse mode. Inflammatory processes can also be treated purposeful.

The **SONOSTAT 133** generates the ultrasonic frequencies 1 MHz as well as 3 MHz. Basically, as higher the ultrasonic frequency, as lower is the penetration of ultrasound. According to this, 3 MHz is recommended for treatments of superficial indications.

1.2 View of SONOSTAT 133

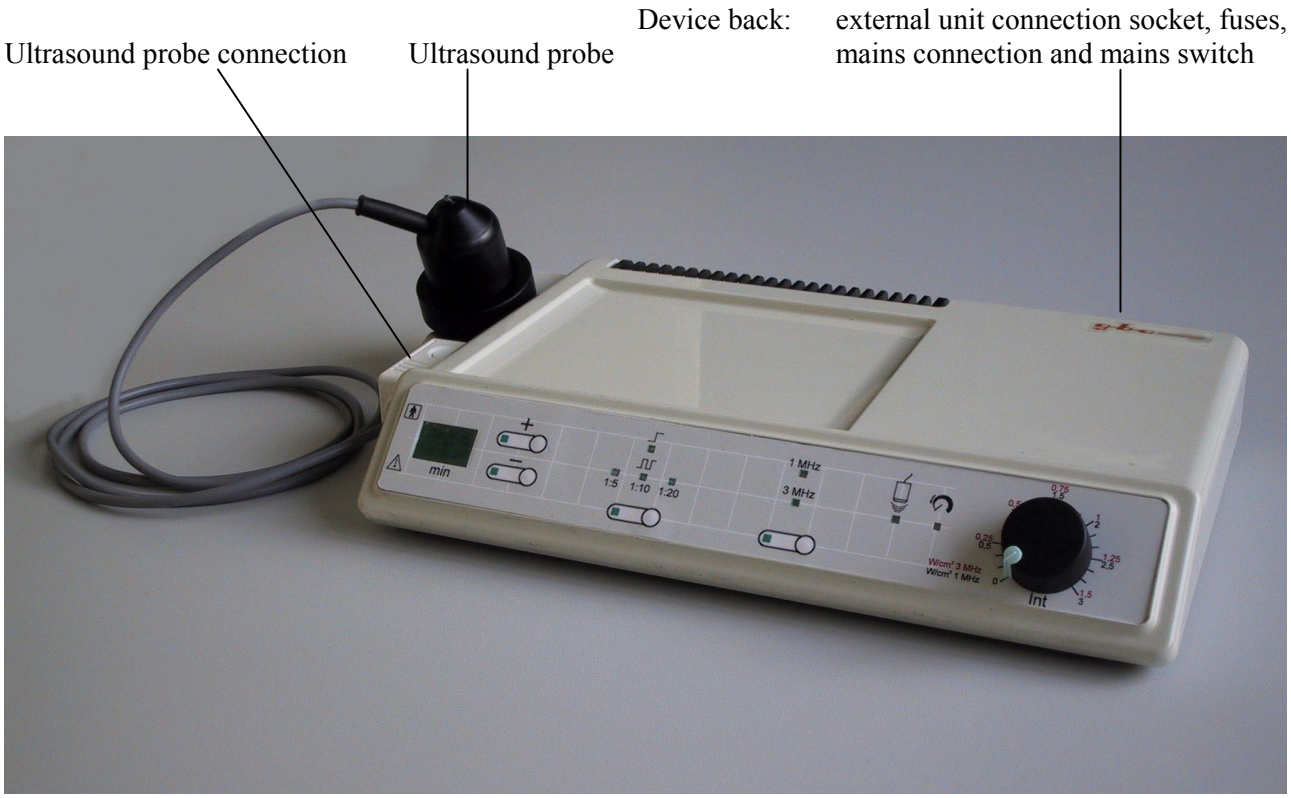


Fig. 1: SONOSTAT 133

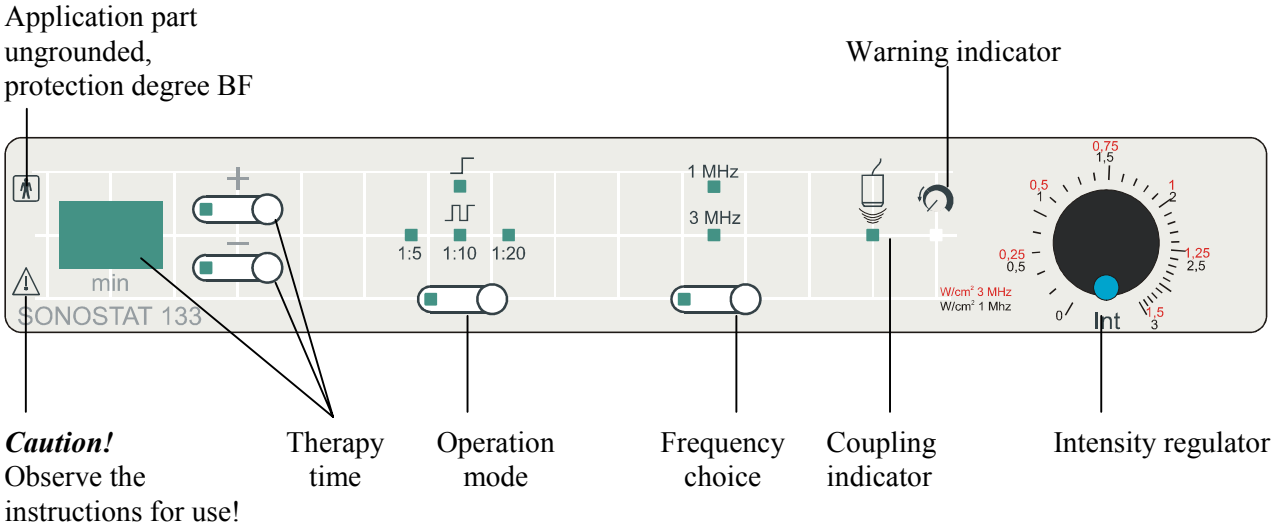


Fig. 2: SONOSTAT 133 - front

1.3 Short instructions

1. Switch on the device through the mains switch at the back of the device. Afterwards the **SONOSTAT 133** carries out an automatic check of all functions. The faultless selftest is indicated in the display:

   - "05" (minutes) = Presetting of the therapy time (if already an ultrasound probe is connected).
   - „ - - “ = no ultrasound probe connected.

2. Connect the ultrasound probe to the socket on the left side of the device.

3. The ultrasound probe will be calibrated. The LED in the ultrasound probe flashes.

4. After the calibration 5 (minutes) are indicated in the display. The LED in the ultrasound probe and the coupling indicator in the **SONOSTAT 133** isn't lit.

5. Select the desired parameters (therapy time, mode of operation, frequency) before the therapy start.

!! Note!

The therapy time can also be set during the therapy.

6. Use contact gel liberally onto the area of the patient to be exposed to the ultrasound. Set up the sound probe flat under light pressure.

7. Increase the ultrasound power with the **intensity regulator** until (normally sensitive) patient has a just noticeable warm feeling. The therapy starts. The LED in the ultrasound probe and the LED of the coupling indicator in the **SONOSTAT 133** are lit.

8. Apply light pressure and keep the ultrasound probe flat against the skin, moving it in circles or even strokes on the parts to be treated.

9. At the end of the treatment the triad beep will sound. The power is automatically switched off. The **LED warning indicator** for the zero position of the **intensity regulator** is lit.

10. Turn the **intensity regulator** to **“0”**.

11. Clean the ultrasound probe from the contact gel.

2 Introduction

2.1 Transport and Installation

The ultrasound therapy device is a portable unit. In the base plate there is a carrying handle in the form of a recessed grip. Each plane surface is appropriate to place the unit. A wall distance of at least 20 cm has to be kept. The device must not be placed in front of radiators.

The **SONOSTAT 133** corresponds to the regulations DIN EN 60601. It is a device of protection class I. Within the scope of the MDD the **SONOSTAT 133** belongs to class IIa .

Warning!

The unit is not designed to be used in non-explosion-proof areas. If it is used in dangerous areas of anaesthesia departments, the possibility of an explosion cannot be excluded.

If the patient and/or the connection cables are directly exposed to a radiator of a medical device for high frequency heat therapy, damage of the device or a threat to the patient cannot be excluded. As a rule, a distance of 3 m is sufficient.

2.2 Connection and Switch-on

The ultrasound therapy device is for the connection with mains voltages from 100 - 240 V $\pm$ 10 %. Irrespective of the mains voltage the device is appropriate for frequencies of 48 to 63 Hz.

2.2.1 Fuses

1. Unplug the mains plug.
2. The device is protected by 2 fuses that are located in a pluggable box at the back of the device.
3. With a screw driver the box can be pulled out of the receiver by the small slot.

The **SONOSTAT 133** is switched on by the mains switch on the back of the device. By this arrangement erroneous, unintended disconnection of the device during normal operations shall be avoided.

After switching on the device, a selftest of all functions will be carried out.

3 Settings

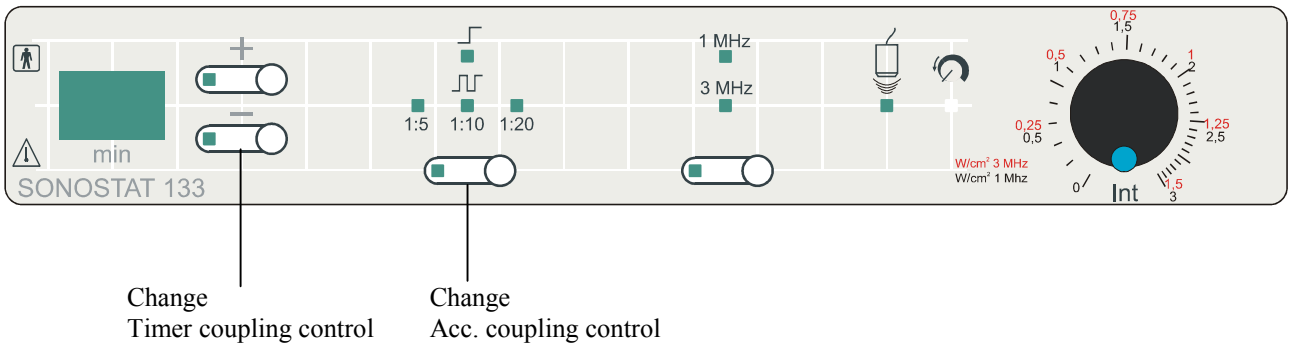


Figure 1: SONOSTAT 133 - Front

Acoustic coupling control
The coupling of the ultrasound probe is signed by an „LED“ on the ultrasound probe. Activation of the acoustic coupling control, i.e. with insufficient coupling sounds an acoustic signal.
You can switch off this acoustic signal.

1. Switch off the unit
2. Switch on the unit while pressing the button for acoustic coupling control.
3. In the display you will see „b0“. The acoustic coupling control is switched off.

To switch on the acoustic coupling control, repeat the same procedure. In the display you will see „b1“. The acoustic coupling control is switched on. Independent of the setting the end of the treatment will be signed by three beep tones.

Timer coupling control
Linkage between coupling control and therapy timer. The timer stops if the ultrasound probe is not coupled. Without this linkage (set to off) the therapy time expires continuously after the first coupling recognition.
You can switch off timer coupling.

1. Switch off the unit
2. Switch on the unit while pressing the button for timer coupling control.
3. In the display you will see „c0“. The timer coupling control is switched off. After coupling one time the timer will decrease until it reached zero.

To switch on the timer coupling control, repeat the same procedure. In the display you will see „c1“. The timer coupling control is switched on. The therapy timer is signed by the flashing point in the display.

4 Description of function

4.1 Operating notes

The ultrasound power can be modified specifically. Except the therapy time modifications can be set only if the **intensity regulator** is "**0**". Please observe the acoustical and optical user support.

4.2 Optical and acoustical user support

An optical user support takes place by the LEDs of the ultrasound probe and the coupling indicator:

LEDs	**Condition of the ultrasound probe and coupling indicator**
flashing	**Ultrasound probe** during calibration.
constantly lit	**Ultrasound probe** is coupled and therapy time will pass.
not lit	**Ultrasound probe** is not coupled and no therapy time will pass.

Table 1: Optical user support

The following table explains the acoustical signals and their meaning:

Type of signal	**Cause**
Alarm approx. 2 s	• error in the selftest • in case of disconnecting the ultrasound probe during the operation • faulty ultrasound contact
Triad beep	• at the end of the therapy.

Table 2: Acoustical user support

4.3 Intensity regulator

The **intensity regulator** serves for setting the ultrasound power. The power is increased by turning it right and is decreased by turning it left. The numerical values are represented circular around the **intensity regulator** in **W/cm²**. The red circle shows the numerical values with the frequency of 3 MHz and the black circle with the frequency of 1 MHz.

The power can be set continuously from 0 to 3 W/cm² at 1-MHz operation and from 0 to 1.5 W/cm² at 3-MHz operation.

	The yellow LED is lit if the **intensity regulator** must be brought in the zero position.

Fig.3: Warning indicator

4.4 Ultrasound probes

Two ultrasound probes are available for treatment. The **SONOSTAT 133** recognises the connected probe.

Warning!

- Do not forget the contact gel!
- Be careful with the ultrasound probe, because rough external influences such as a mechanical shock or impact can alter its characteristics. We recommend to carry out a visual examination at least once a year to check for fissures that allow liquids to enter, as well as regarding the integrity of the cables and connectors.

	Power for			
	5 cm² ultrasound probe		**2.5 cm² ultrasound probe**	
1 MHz	0 to 15 W	0 to 3 W/cm²	0 to 15 W	0 to 3 W/cm²
3 MHz	0 to 7.5 W	0 to 1.5 W/cm²	0 to 7.5 W	0 to 1.5 W/cm²

Table 3: Range of ultrasound power

Note!

- The coupling status of the ultrasound probe is indicated by the LED in the ultrasound probe housing and by the LED of the coupling indicator in the **SONOSTAT 133**. The LEDs aren't lit in case of insufficient coupling.
- If the ultrasound probe is not contacted to the patient during therapy, no therapy time will pass. After reestablishing the contact to the patient the therapy time will pass further. The ultrasound probe can be removed at any time.

	The LED of the coupling indicator is lit if the ultrasound probe is coupled. The LED is lit synchronously with the LED in the ultrasound probe.

Fig. 4: Coupling indicator

4.5 Therapy time

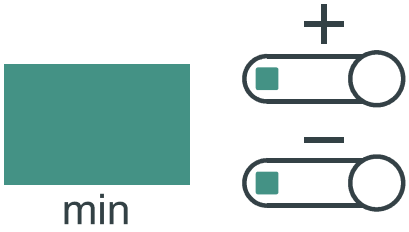
	The therapy time can be set in minute steps between 1 and 15. The selected therapy time is indicated in the display. The presetting of the therapy time is 5 min. With the **therapy time-keys** + and – the time can be changed up and down.

Fig. 5: Therapy time keys with display

Note!

- The therapy time can be modified during the treatment.
- At the end of the therapy time the ultrasound power is switched off, the triad beep is sounded 3 x and the LED of the warning indicator for the zero position of the **intensity regulator** is lit.
  - Turn the **intensity regulator** to "**0**".
  - Parameters and modifications of the last therapy are retained.
  - The therapy time is 0 min.
  - The therapy can be continued by setting a new therapy time and turning on the intensity.

4.6 Operation mode

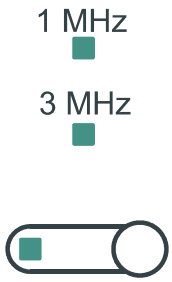
By repeated pressing of the **operation mode key** it is switched between continuous sound and impulse sound. Within the impulse sound a sound break can be set with a certain pulse-duty factor. The chosen mode of operation is indicated by the appropriate LED.

The power is delivered to the permanent sound continuously. The **SONSOTAT 133** is in the CW operation.

The **operation mode key** is locked during the treatment.

Fig. 6: Mode of operation key with LEDs

4.7 Frequency choice



With the **frequency choice key** frequencies between 1 and 3 MHz can be chosen. The chosen frequency is indicated by the appropriate LED.

The **frequency choice key** is locked during the treatment.

Fig. 7: Frequency choice-key with LEDs

5 Therapy

The duration of treatment depends not only on the size of the body area being treated and the size of the treatment probe used, but also on the relative stage of the disease.
Treatment with ultrasound lasting 5 minutes is usually sufficient for an average-size zone. With disorders accompanied by changes in the tissue structure, such as sclerodermatitis, arthrosis, etc., it is frequently advantageous to lengthen the exposure to about 10 minutes per field. Treatment zones extending over some length, such as courses of nerves, are divided up into several fields, which are exposed to ultrasound one after another for 5 (or 10) minutes.

The golden rule is: the more acute the process, the lower the intensity to be used, and the more chronic the process, the greater the intensity to be used. Take care with the dosage when beginning treatment. The is particularly advisable when treating the trunk of the body with ultrasound: don't forget that there may be sensitive organs close by *(see chapter 5.2)*. The upper limit of the permissible intensity is generally signalled by the occurrence of periosteal pain, provided the patient does not exhibit any sensory disturbance. Treatment can be regarded as therapeutically appropriate when the intensity is such that a just detectable feeling of warmth is produced in the normally sensitive patient. Underdosage runs the risk of being ineffectual, and thus a waste of time.

The number of treatments required (carried out daily or each second day, depending on the circumstances) depends on how successful the treatments are. Usually only one or two further treatments are necessary after the symptoms subside. A total of 10 to 15 treatments generally suffices. Where improvement is only slow, continue therapy until a satisfactory result obtained. Even where there is an apparent worsening, we do not recommend giving up treatment before third or fourth sitting. If deterioration continues, it is advisable to check the diagnosis (e.g. slipped disk with sciatica, foci). It is frequently the case that structure-changing processes can be favorably influenced by an extended therapy of up to 40 treatment sessions.

Generally the following procedure is established:

1. Connect the ultrasound probe to the socket on the left side of the device.
2. The ultrasound probe will be calibrate. During the calibration The LED in the ultrasound probe flashes.
3. The LEDs of the actual parameters are lit. If desired you can change these before the therapy starts.
4. Set the desired mode of operation by pressing the **operation mode key**.
5. Set the desired frequency (1 or 3 MHz) by pressing the **frequency choice key**.
6. In the display the therapy time is indicated (pre-setting 5 minutes). Set by means of the **therapy time keys** the desired therapy time. The therapy time can be also modified during the treatment.
7. Spread contact gel liberally onto the area of the patient to be exposed to the ultrasound. Set up the sound probe flat under light pressure.
8. Increase the ultrasound power with the **intensity regulator** until the (normally sensitive) patient has a just noticeable warm feeling. The therapy starts. The LED in the ultrasound probe and the LED of the coupling indicator in the **SONOSTAT 133** are lit.
9. Apply light pressure and keep the ultrasound probe flat against the skin, moving it in circles or even strokes on the parts to be massaged.
10. At the end of the treatment the triad beep will sound. The power is automatically switched off. The **LED warning indicator** for the zero position of the **intensity regulator** is lit.
11. Turn the **intensity regulator** to **"0"**.
12. Clean the ultrasound probe of the contact gel.

!! Note!

Only the therapy time can be also modified during the therapy.

5.1 Combination therapy with current stimulation or HiToP ®

The **SONOSTAT 133** may be used with **DUODYNATOR 119** and **HiToP®** therapy devices of gbo Medizintechnik AG. Using the **SONOSTAT 133** in combination with different units than the above mentioned units leads to extinction of gbo Medizintechnik AG´s product liability and warranty.

There is a special input socket provided in the device back of the **SONOSTAT 133** for connecting such a unit. However, for reasons of safety the current connection is interrupted device-internal if or as long as the intensity value amounts to 0.0 W/cm^2 or 0.0 W.

Warning!

- If during the treatment an electrode must be put on at another place, always turn back first the intensity of the current on zero.
- **Observe the operating instructions of the connected current stimulation or HiToP® therapy device!**
- Due to the acidification of the contact gel, the ultrasound therapy cannot be operated with the **Galvanic** current type.
- It is recommended not to exceed the current density of 2 mA/cm^2 in all electrode surfaces.
- Deactivate **the current monitoring** of the connected current stimulation or **HiToP®** therapy device **only** if it comes to problems with the coupling of the ultrasound probe! Since then the current monitoring of the connected therapy device would switch off its current!

For the combination therapy the following method of approach is recommended:

In the **DUODYNATOR 119:**	In the **HiToP®** therapy device:
1. Select the current type. 2. Set the desired modifications. 3. The white plug has positive polarity in the basic setting, whereas the counterelectrode – the metallic ultrasound probe surface – is negative. Connect the white plug of the patient cable with the neutral electrode and black with the **SONOSTAT 133**. 4. Apply the neutral electrode.	1. Select the current type. 2. Set the desired modifications. 3. Connect one plug of the patient cable with the neutral electrode and the other plug with the **SONOSTAT 133**. 4. Apply the neutral electrode.
In the **SONOSTAT 133**:	
5. Connect the ultrasound probe to the socket on the left side of the device. 6. The ultrasound probe will be calibrated. During the calibration The LED in the ultrasound probe flashes. 7. The LEDs of the actual parameters are lit. If desired you can change these before the therapy starts. 8. Set the desired mode of operation by pressing the **operation mode key**. 9. Set the desired frequency (1 or 3 MHz) by pressing the **frequency choice key**. 10. In the display the therapy time is indicated (pre-setting 5 minutes). Set with the help of the **therapy time keys** the desired therapy time. The therapy time can also be modified during the treatment. 11. Spread contact gel liberally onto the area of the patient to be exposed to the ultrasound. Set up the sound probe flat under light pressure.	
In the **DUODYNATOR 119** or in the **HiToP®** therapy device:	
12. Set the current intensity in the current stimulation device or **HiToP®** therapy device by turning **on** the **intensity regulator** until the desired stimulation effect occurs. If the patient experiences a pain, reduce the intensity.	
In the **SONOSTAT 133**:	
13. Increase the ultrasound power with the **intensity regulator** until the (normally sensitive) patient has a just noticeable warm feeling. The therapy starts. The LED in the ultrasound probe and the LED of the coupling indicator in the **SONOSTAT 133** are lit. 14. Apply light pressure and keep the ultrasound probe flat against the skin, moving it in circles or even strokes on the parts to be massaged. 15. At the end of the treatment the triad beep will sound. The power is automatically switched off. The **LED warning indicator** for the zero position of the **intensity regulator** is lit. 16. Turn the **intensity regulator** to **"0"**. 17. Clean the ultrasound probe of the contact gel.	
In the DUODYNATOR 119 or **in the HiToP ®** - therapy device:	
18. At the end of the therapy time the triad gong will sound three times. The **intensity regulator** automatically reverts to "0.0".	

5.2 Contraindications

An exact diagnosis must be made before starting therapy. The diagnosis determines which treatment with ultrasound is indicated at all.
Regardless of the low dosage and the relatively wide field of application, distinct contraindications have become evident. The “harmfulness” frequently discussed in the literature is of secondary importance, because no organic damage can be caused with the stated low dose, provided when static exposure to ultrasound is avoided.

Warning!

Ultrasound should not be used in case of:

- Changes to the skin, particularly with infectious diseases and birthmarks
- Tumorous diseases in all stages
- Feverish conditions
- Poor general condition and general atrophy
- Active tuberculosis, regardless of stage and localization
- Acute inflammations
- Stomach ulcers
- Following recent Thoriam-X treatment, X-ray depth treatment
- Diabetes mellitus
- Pregnancy
- Vascular diseases of the extremities (thrombophlebitis, thrombosis, varicosis)
- Disorders of coagulation of blood
- Acute join rheumatism.

Near these disease groups one should be troubled to expel certain organs of a direct treatment. The following organs must not be treated directly:

- Eyes, brain and spinal marrow
- Laminectomy-related spinal incisions
- Anesthetized areas
- Heart and lungs
- **Do no expose** of heart segments with functional heart complaints.
- **Do no expose** of the epiphysis zones of children.

!! Note!

This list raises no claim to completeness. In the individual case the doctor always decides on contraindications and criteria of treatment.

6 Behavior in case of failures

The following failures will indicated by the ultrasound-therapy device optically and acoustically. Most can be repaired if you proceed by the following suggestions. The failure messages which are indicated in the display are in this chapter by ♦ marked. Other failures are by • marked.

In general:

1. The device is protected against faulty use for a large extent. That means: The device does not carry out a function or modification erroneously entered through **intensity regulator** or **modification key**.
2. The acoustic signal will sound.
3. The display shows an error message.
4. If the operator does not react to the respective notes, the previous correct status will be restored after a timeout.

Failure conditions:

♦ F1, F2, F3, F4 – With the selftest of the device a failure has appeared.

1. Switch off and on again.
2. If the failure occurs again, the device is out of function. Please contact a service agent authorized by the manufacturer.

♦ E1 – A not suitable or faulty ultrasound probe is connected.

- You have connected a not suitable ultrasound probe: Use the suitable ultrasound probes.
- The ultrasound probe is faulty:
  1. Disconnect the ultrasound probe.
  2. Clean the resonance plate of the ultrasound probe thoroughly damp, because, possibly, oxidations have appeared. This can lead to problems during the calibration of the ultrasound probe.
  3. Connect the ultrasound probe again, the ultrasound probe will be calibrated again.
  4. If the failure occurs again, the device is out of function. Please contact a service agent authorized by the manufacturer.

♦ E2 – The ultrasound probe is not connected correctly or was disconnected during the therapy.

1. Check the locking, the cables and the connections.
2. Should the failure not be repaired, switch off the ultrasound therapy device and on again.
3. If the failure occurs again, the ultrasound probe is faulty. Please contact a service agent authorized by the manufacturer.

♦ E3 – The ultrasound therapy device has switched off itself because of overtemperature.

– Let cool down the ultrasound therapy device, i.e. you switch off the ultrasound therapy device and let it cool.

- ***LED of warning indicator flashes***

– Turn the **intensity regulator** in the zero position.

7 Maintenance

Functionality, reliability and safety characteristics of ultrasound therapy devices are only guaranteed if properly used in accordance with the operating instructions. Safety control, maintenance, repair and modifications shall be carried out by the manufacturer or the service agents authorized by him. In case of a failure, parts which influence the safety of the device shall be replaced only by original spare parts of the manufacturer. The electric installation shall be carried out in accordance with the requirements of VDE/IEC. **The device does not contain any parts which need maintenance work done by the user.**

7.1 Safety controls

The device is subject to the provisions of the MDD. The safety controls have to be carried out on the basis of this directive. Thereby, the operator regulation has to be especially observed. Irrespective of the legal rules or beyond the scope of the MDD, it is recommended to have the device checked by the manufacturer or by a service agency authorized by him at 12-months intervals.

The check shall consist of at least the following:

- Electrical safety check in accordance with the test plan of the manufacturer,
- Check of the device in respect of external integrity,
- Check of all display and operating elements in respect of damage,
- Check of all inscriptions in respect of legibility.

7.2 Cleaning, disinfection and care

For cleaning and disinfection of the device and its accessories there should not be used any agents containing higher portions of phenol derivates, alcohol, compounds of chlorine or peracetic acid. It is recommended to use disinfectants on aldehyde basis.
The device is not suited for heat sterilization or for sterilization with gases.

Warning!

Before cleaning or disinfection unplug the mains plug out of the socket!

The device and the ultrasound probes are suited for wiping disinfection. It has to be observed that no liquids enter the device or the ultrasound probes. Never shall the plug or socket get wet. For cleaning or disinfection the device must not be dizzled.

!! Note!

After each treatment session, be sure to thoroughly clean the resonance plate of the treatment probe to prevent oxidation.

8 Warnings and Safety Precautions

Warning!!

- In case of patients with implanted electronic device carry out electrical stimulation treatment only after having checked whether there is any risk.

- Pieces of jewellery, glasses and other metal parts have to be taken off during the treatment.

- Turn off cellular phones and radiophone or place them in a distance of 3 m from the device.

- Cardiac pacemakers can extremely be disturbed. In these cases the therapy should be only carried out under continuous pulse and ECG control.

- If the patient and/or the connection cables are in direct range of a high-frequency, short-wave or micro-wave therapeutic device, a damage to the device or an injury of the patient cannot be excluded. Please keep a distance of 3 m.

- The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anaesthesia departments, the possibility of an explosion cannot be excluded.

- Are contraindicated *(see also chapter 5.2)*:
  - Changes to the skin, particularly with infectious diseases and birthmarks
  - Tumorous diseases in all stages
  - Feverish conditions
  - Poor general condition and general atrophy
  - Active tuberculosis, regardless of stage and localization
  - Acute inflammations
  - Stomach ulcers
  - Following recent Thoriam-X treatment, X-ray depth treatment
  - Diabetes mellitus
  - Pregnancy
  - Vascular diseases of the extremities (thrombophlebitis, thrombosis, varicosis)
  - Disorders of coagulation of blood
  - Acute join rheumatism.

- Near these disease groups one should be troubled to expel certain organs of a direct treatment. The following organs must not be treated directly:

  - Eyes, brain and spinal marrow
  - Laminectomy-related spinal incisions
  - Anaesthetised areas
  - Heart and lungs
  - **Do no expose** of heart segments with functional heart complaints.
  - **Do no expose** of the epiphysis zones of children.

!! Note!

This list raises no claim to completeness. In the individual case the doctor always decides on contraindications and criteria of treatment.

- In case of all visible failures contact immediately gbo Medizintechnik AG or one of the service agencies authorized by gbo Medizintechnik AG .

9 Explanation of the signs used

CE - conformity sign

Caution!
Observe the instructions for use!

Application part ungrounded, protection degree BF

The device connection socket which serves the electric connection with an external current therapy device (e.g.**, DUODYNATOR 119** or **HiToP® 182**).

This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment.

10 Technical data

Mains voltage and frequency:	Wide input power supply 100 - 240 V AC ± 10 % with 48 – 63 Hz	
Current consumption:	with 120 V: max. 0.8 A with 230 V: max. 0.4 A	
Mains fuses:	2 x 1 A T	
Max. Power output:	15 W with 1 MHz and 7.5 W with 3 MHz	
Impulse relation:	CW, 1:5, 1:10 and 1:20	
Impulse sound frequency:	100 Hz	
Current type:	Ultrasound 1 or 3 MHz	
Ultrasound frequency:	1 and 3.325 – 3.405 MHz	
Ultrasound probes:	2.5 cm^2 and 5 cm^2 effective emitting surface	
MDD Device class:	IIa	
Safety class:	I	
Protection degree:	BF	
Protection against ingress of liquids:	IP X1	
Dimensions:	6.5 cm x 23 cm x 37 cm (H x T x B)	
Weight:	1.9 kg without accessories	
Color:	white RAL 9002	
Environmental conditions:	Operation of the device:	Temperature range 10 °C... 40 °C Relative humidity 30... 75%
	Transport and storage:	Temperature range 5 °C... 50 °C Relative humidity < 90 %, not condensing

gbo Medizintechnik AG reserves the right to modify the design and specification without prior notice.

11 Accessories

Article designation		Article number
SONOSTAT 133 Extent of supply	1 **SONOSTAT 133** 1 Ultrasound probe 5 cm^2 (1 and 3 MHz) 1 Contact gel, 250 ml 1 User manual, German	023-0-0133
Contact gel, 250 ml		45-39-128EH725
Ultrasound probe 2.5 cm^2 (1 and 3 MHz)		023-0-0140
Ultrasound probe 5 cm^2 (1 and 3 MHz)		023-0-0141
User manual **SONOSTAT 133**, German		023-7-0001
User manual **SONOSTAT 133**, English		023-7-0002

12 Appendix

Index

Notes in accordance with EC directive and Medical Device Directive (MDD)

The **SONOSTAT 133** is a line-powered ultrasound-therapy device of the protection class **I**.

The device is in accordance with the EC directive for medical devices (93/42/EWG) and therefore carries the CE sign with the registration number of the notified body for medical devices. The according graphical symbol is placed on the type plate.

According to the MDD, **SONOSTAT 133** is a class **IIa** device.

The manufacturer is only responsible for the safety, operational reliability and functionality of the device if:

- the device is used in accordance with the instructions for use;
- the electrical installation of the location where the device will be used meets the respective current requirements of electrical safety;
- the device is not used in hazardous environments and humid locations;
- mountings, amplifications, re-adjustments, modifications or repair works are carried out only by personnel authorized by the manufacturer;
- the operator regulation of this EC directive is observed within the scope of MDD.

Technical support may be obtained by the manufacturer, dealers or service authorized by the manufacturer. The product's duration of life as scheduled by the manufacturer is 10 years.

SONOSTAT 133 is an electronic device. For its disposal the according regulations for electronic devices have to be observed.

On request, the manufacturer will provide you with further technical descriptions for all repairable parts of the device, such as circuit diagrams, spare parts lists, and adjustment instructions as far as these are necessary for the qualified technical staff of the operator.

Comments on electromagnetic compatibility (EMC)
Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical, electrical devices may be influenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when using accessories which are listed in the EC declaration of conformity. The usage of other accessories my cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with other devices than current stimulation units of the brand gbo. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2 (*)	Class A	
Voltage fluctuation/flicker emissions, IEC 61000-3-3 (*)	Complies	
(*) Note: For devices with a power consumption between 75 W and 1000 W only.		

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles 60% dip) 70% U_τ for 25 cycles 30% dip) <95% U_τ for 5 s (>5% dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{eff}	$d=1,2\sqrt{P}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d=1,2\sqrt{P}$ for 80 MHz to 800 MHz $d=2,3\sqrt{P}$ for 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.			
Rated power of the transmitter (W)	**Separation distance according to the tranmission frequency (m)**		
	150 kHz to 80 MHz $d=1,2\sqrt{P}$	**80 MHz to 800 MHz $d=1,2\sqrt{P}$**	**800 MHz to 2,5 GHz $d=2,3\sqrt{P}$**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

Notes

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